K003921

510(k) SUMMARY

DENTSPLY

JAN 2 4 2001

NAME & ADDRESS: **DENTSPLY International**
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
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P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: December 19, 2000

TRADE OR PROPRIETARY NAME: Dyract Cem® LCI Compomer

CLASSIFICATION NAME: Dental Cement 872.3275

PREDICATE DEVICES: Dyract® Flow Flowable Compomer K982395

DEVICE DESCRIPTION: Dyract Cem® LCI Compomer is a light-curing fluoride-releasing compomer for luting of composite and ceramic inlays and onlays. Dyract Cem® LCI Compomer is pre-dosed in Compules® tips for direct application onto the restoration or tooth preparation.

INTENDED USE: Dyract Cem® LCI Compomer is indicated for adhesive cementation of ceramic or composite inlays, onlays and crowns.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in Dyract Cem® LCI Compomer have been used in the predicate device.

The safety of these components was addressed in the K982395 submission (predicate device); therefore, we do not believe that additional biocompatibility testing is necessary.

We believe that the prior use of the components of Dyract Cem® LCI Compomer in a legally marketed predicate device, the performance data provided, and the previous biocompatibility test results support the safety and effectiveness of Dyract Cem® LCI Compomer for the indicated uses.

Substantial Equivalence Comparison: (cont'd.)

ID of Predicate Device: (cont'd.)

The Directions for Use of the predicate device, Dyract® Flow Flowable Compomer (K982395), can be found in Exhibit A.

Statement of Similarities and/or Differences with Marketed Device:

Similarities Between Predicate Device and Dyract Cem® LCI Compomer
Substantially equivalent in intended use and components
Contain releasable fluoride
Visible light cured materials
Moderately filled, low viscosity materials, may be dispensed from a compule

Differences	**Predicate Device**	**Dyract Cem® LCI Compomer**
Formulation	Contains pigments	Contains no pigments
Aerosil	Contains A380	Contains A200

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K003921
Trade Name: Dyract Cem® LCI Compomer
Regulatory Class: II
Product Code: EMA
Dated: December 19, 2000
Received: December 20, 2000

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K003921

Device Name: **Dyract Cem® LCI Compomer**

Indications for ~~Use~~:

Indicated for adhesive cementation of ceramic or composite inlays, onlays and crowns.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003921

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)